



12-16-03

Docket No: AM101017
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of: Eric L. Lien, Charles F. Kuhlman
Application No.: 10/663,923 Group Art No.: Not Yet Assigned
Filed: September 16, 2003 Examiner: Not Yet Assigned
For: INFANT FORMULA CONTAINING PARTIALLY HYDROLYZED
ISOLATED SOY PROTEIN WITH A REDUCED PHYTATE
CONTENT
Confirmation No.: Not Yet Assigned
Customer Number: 25291

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

1. Preliminary Statements

In accordance with 37 CFR 1.97 and 1.98, Applicants submit herewith patents, publications, or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) the information is material to the examination of this application; (iii) additional information material to the examination of this application does not exist; (iv) the information, protocols, results and the like reported by third parties are accurate or enabling; or (v) the information constitutes prior art to the subject invention.

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EU947816309US addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

December 15, 2003
Date

Bubinea D. Owens
Bubinea D. Owens

2. Identification of Time of Filing

This Information Disclosure Statement

- a. ☒ is filed within three months of the filing date of the application.
- b. ☐ is filed before the mailing date of a first Office Action on the merits.
- c. ☐ is filed before the mailing date of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- d. ☐ is filed after the period specified in 2(a), 2(b) or 2(c) above, but before the mailing date of a final action under 37 CFR 1.311. This statement includes a certification under 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p).
- e. ☐ is filed after the mailing date of a final action or Notice of Allowance but before payment of the issue fee. This statement includes (i) a certification under 37 CFR 1.97(e), and (ii) the fee set forth in 37 CFR 1.17(p).

3. ☐ Certification under 37 CFR 1.97(e) and 1.704(d)
The undersigned attorney certifies

- a. ☐ that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement, or
- b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the statement.
- c. ☐ The undersigned attorney certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign application patent office in a counterpart foreign application and was not received by any individual designated in 37 CFR 1.56(c) more than thirty (30) days prior to the filing of the statement.

☒ Newly Cited Information

A legible copy of the patents, publications or other information cited on the attached form PTO 1449 is enclosed, except that no copy of a pending U.S. application is enclosed, and if this patent application was filed or entered the national stage after June 30, 2003, no copy of a U.S. patent or U.S. patent application publication is enclosed.

☐ Previously Cited Information

No copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed because it has been previously cited by or submitted to the Office in a prior application which is relied upon for an earlier filing date under 35 USC 120.

Prior application is Application Number _____, filed on _____ of _____ for _____

- ☐ Concise Explanation
Documents cited above which are not in the English Language
- a. ☐ have been explained in the specification.
- b. ☐ have an abstract (or other concise explanation) in English enclosed or if readily available a translation into English of the document is enclosed.

Form PTO-1449 is enclosed in duplicate.

- ☐ Fees
- ☐ Fee for filing under 37 CFR 1.97(c) or (d) Fee: \$180.00

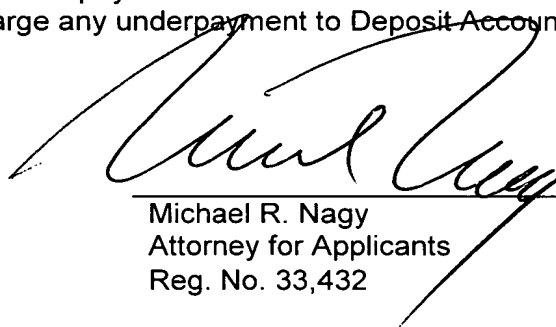
Method of Payment of Fees:

Charge Deposit Account No. 01-1425 in the amount of \$0.00

A duplicate of this statement is enclosed.

Instructions as to Overpayment/Underpayment:

Credit any overpayment and charge any underpayment to Deposit Account No. 01-1425.



Michael R. Nagy
Attorney for Applicants
Reg. No. 33,432

Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940
Tel. No. (484) 865-8616

Substitution for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known	
Application Number		10/663,923	
Filing Date		September 16, 2003	
First Named Inventor		Eric L. LIEN	
Group Art Unit		Not Yet Assigned	
Examiner Name		Not Yet Assigned	
Attorney Docket Number		AM101017	

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number (If known)	Kind Code (If Known)			
	1.	6,284,502		Maenz, et al	09-04-2001	
	2.	6,313,273	B1	Thomas, et al.	11-06-2001	
	3.	5,248,804		Nardelli, et al.	09-28-1993	
	4.	3,970,520		Feldman, et al.	07-20-1976	
	5.	4,100,024		Adler-Nissen	07-11-1978	
	6.	4,443,540		Chervan, et al.	04-17-1984	
	7.	6,126,973		Tsumura, et al.	10-03-2000	
	8.	6,221,423	B1	Cho, et al.	04-24-2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (If Known)				
	9.							<input type="checkbox"/>

OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	10.	SAMUEL J. FOMON, "Isolated Soy Protein-Based Formulas", "Formulas Available in the United States", Nutrition of Normal Infants, 1993, page 428.	<input type="checkbox"/>
	11.	HAROLD L. WILCKE, et al., "Soy Protein and Human Nutrition", Academic Press, Inc., 1979, pages 19-51.	<input type="checkbox"/>
	12.	JOSEPH A. MAGA, "Phytate: Its Chemistry, Occurrence, Food Interactions, Nutritional Significance, and Methods of Analysis", Journal of Agricultural and Food Chemistry, 1989, Vol. 30, pages 1-9.	<input type="checkbox"/>
	13.	"Soy Protein-based Formulas: Recommendations for Use in Infant Feeding", Pediatrics, 1998 Vol. 101 No. 1, pages 148-153	<input type="checkbox"/>
	14.	J. R. FORD, "Phytic Acid Removal from Soybeans by a Lipid Protein Concentrate Process", Journal of the American Oil Chemists' Society, 1978 Vol. 55 pages 371-374.	<input type="checkbox"/>
	15.	BO LONNERDAL, et al., "Effect of reducing the phytate content and of partially hydrolyzing the protein in soy formula on zinc and copper absorption and status in infant rhesus monkeys and rat pups", Amer. J. Clin. Nutr., 1999, Vol. 69 (3), pages 490-496	<input type="checkbox"/>
	16.	A. W. BURKS, et al., "Prospective oral food challenge study of two soybean protein isolates in patients with possible milk or soy protein enterocolitis", Pediatr. Allergy Immunol., Vol. 5, pages 40-45.	<input type="checkbox"/>
	17.	A. W. BURKS, et al., "Identification and Comparison of Differences in Antigens In Two Commercially Available Soybean Protein Isolates", J. Food Science, 1988 Vol. 53 (5), pages 1456-1459	<input type="checkbox"/>
	18.	L. JANAS, et al., "Tolerance of soy formulas with reduced phytate/phytoestrogens fed to healthy, term infants", Poster presented at the second international symposium on the role of soy in preventing and treating chronic disease, Brussels, Belgium, September, 1996	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitution for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/663,923
				Filing Date	September 16, 2003
				First Named Inventor	Eric L. LIEN
				Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned				
Attorney Docket Number	AM101017				

DEC 15 2003
 JCS6
 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number (If known)	Kind Code (If Known)			
	1.	6,284,502		Maenz, et al	09-04-2001	
	2.	6,313,273	B1	Thomas, et al.	11-06-2001	
	3.	5,248,804		Nardelli, et al.	09-28-1993	
	4.	3,970,520		Feldman, et al.	07-20-1976	
	5.	4,100,024		Adler-Nissen	07-11-1978	
	6.	4,443,540		Chervan, et al.	04-17-1984	
	7.	6,126,973		Tsumura, et al.	10-03-2000	
	8.	6,221,423	B1	Cho, et al.	04-24-2001	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (If Known)				
	9.							<input type="checkbox"/>

OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T
	10.	SAMUEL J. FOMON, "Isolated Soy Protein-Based Formulas", "Formulas Available in the United States", Nutrition of Normal Infants, 1993, page 428.	<input type="checkbox"/>	
	11.	HAROLD L. WILCKE, et al., "Soy Protein and Human Nutrition", Academic Press, Inc., 1979, pages 19-51.	<input type="checkbox"/>	
	12.	JOSEPH A. MAGA, "Phytate: Its Chemistry, Occurrence, Food Interations, Nutritional Significance, and Methods of Analysis", Journal of Agricultural and Food Chemistry, 19892, Vol. 30, pages 1-9.	<input type="checkbox"/>	
	13.	"Soy Protein-based Formulas: Recommendations for Use in Infant Feeding", Pediatrics, 1998 Vol. 101 No. 1, pages 148-153	<input type="checkbox"/>	
	14.	J. R. FORD, "Phytic Acid Removal from Soybeans by a Lipid Protein Concentrate Process", Journal of the American Oil Chemists' Society, 1978 Vol. 55 pages 371-374.	<input type="checkbox"/>	
	15.	BO LONNERDAL, et al., "Effect of reducing the phytate content and of partially hydrolyzing the protein in soy formula on zinc and copper absorption and status in infant rhesus monkeys and rat pups", Amer. J. Clin. Nutr., 1999, Vol. 69 (3), pages 490-496	<input type="checkbox"/>	
	16.	A. W. BURKS, et al., "Prospective oral food challenge study of two soybean protein isolates in patients with possible milk or soy protein enterocolitis", Pediatr. Allergy Immunol., Vol. 5, pages 40-45.	<input type="checkbox"/>	
	17.	A. W. BURKS, et al., "Identification and Comparison of Differences in Antigens In Two Commercially Available Soybean Protein Isolates", J. Food Science, 1988 Vol. 53 (5), pages 1456-1459	<input type="checkbox"/>	
	18.	L. JANAS, et al., "Tolerance of soy formulas with reduced phytate/phytoestrogens fed to healthy, term infants", Poster presented at the second international symposium on the role of soy in preventing and treating chronic disease. Brussels, Belgium. September, 1996		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.